DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 27, 2014

Titan Spine, LLC
% Christine Scifert, MS, MEM
Memphis Regulatory Consulting, LLC
3416 Roxee Run Cove
Bartlett, Tennessee 38133

Re: K141953
Trade/Device Name: Endoskeleton® System (Endoskeleton® TA Interbody Fusion Device, Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TO Interbody Fusion Device, Endoskeleton® TT Interbody Fusion Device, Endoskeleton® TC Interbody Fusion Device, Endoskeleton® TL Interbody Fusion Device, Endoskeleton® TA Vertebral Body Replacement)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD, ODP, MQP
Dated: October 3, 2014
Received: October 6, 2014

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141953

Device Name
Endoskeleton(R) System

Indications for Use *(Describe)*
The ENDOSKELETON® TA Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the device. The device may be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TAS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TO IBD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TT IBD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TC is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The Endoskeleton® TC is indicated to be used with supplemental fixation and autograft bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

The Endoskeleton® TL IBD is indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. This device is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients with non-fusion spinal surgery at the involved level(s) may be treated with the device. It is indicated to be used with autograft bone.

The ENDOSKELETON® TA VBR is for use in the thoracolumbar spine (T1 – L5) to replace all or part of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The ENDOSKELETON® TA VBR is intended for use with supplemental internal spinal fixation systems. The ENDOSKELETON® TA VBR may be used with bone graft material or bone graft substitute.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
Endoskeleton® System
October 21, 2014

Company:	Titan Spine, LLC 6140 W. Executive Drive, Suite A Mequon, WI 53092, USA
Establishment Registration:	3006340236
Primary Contact:	Christine Scifert Phone: 901-831-8053
Company/Secondary Contact:	Jane Rodd Phone: 866-822-7800 Fax: 262-242-7802
Trade Name:	Endoskeleton® System • ENDOSKELETON® TA Interbody Fusion Device • Endoskeleton® TAS Interbody Fusion Device • Endoskeleton® TO Interbody Fusion Device • Endoskeleton® TT Interbody Fusion Device • Endoskeleton® TC Interbody Fusion Device • Endoskeleton® TL Interbody Fusion Device • ENDOSKELETON® TA Vertebral Body Replacement
Common Name:	Intervertebral body fusion device Intervertebral fusion device with bone graft, cervical Intervertebral fusion device with bone graft, lumbar Intervertebral fusion device with integrated fixation, lumbar Spinal vertebral body replacement device
Classification:	Class II
Regulation Number:	21 CFR 888.3080 (Intervertebral body fusion device) 21 CFR 888.3060 (Spinal intervertebral body fixation orthosis)

Panel: 87- Orthopedic

Product Code: OVD, MAX, ODP, MQP

Device Description:
This traditional 510(k) is intended to modify the surface treatment of Endoskeleton devices.

The Endoskeleton system is an interbody and vertebral body system comprised of a variety of implant sizes and geometries to accommodate various patient anatomy and pathology. The modified surface technology provides a microscopic roughened surface with nano-scale features. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI).

Indications for Use:
The ENDOSKELETON® TA Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the device. The device may be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TAS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TO IBD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TT IBD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

The Endoskeleton® TC is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The Endoskeleton® TC is indicated to be used with supplemental fixation and autograft bone.

The Endoskeleton® TL IBD is indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. This device is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients with non-fusion spinal surgery at the involved level(s) may be treated with the device. It is indicated to be used with autograft bone.

The ENDOSKELETON® TA VBR is for use in the thoracolumbar spine (T1 – L5) to replace all or part of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The ENDOSKELETON® TA VBR is intended for use with supplemental internal spinal fixation systems. The ENDOSKELETON® TA VBR may be used with bone graft material or bone graft substitute.

Substantial Equivalence:

The proposed modifications to the Endoskeleton® devices are identical to predicate devices previously cleared by Titan Spine:

- Predicate: Endoskeleton TAS – K111626
- Other predicates: Endoskeleton TA - K080615, Endoskeleton TT – K083714, Endoskeleton TO – K102067, Endoskeleton TC – K100889, Endoskeleton TL – K140055 and Endoskeleton TA VBR – K032812

The subject Endoskeleton® device is identical to the predicate devices with respect to indications for use, design, dimension, and materials. The only difference to the currently marketed devices is the change in surface treatment.

Technological Characteristics

There are no changes between the predicate devices and the subject devices with respect to indications for use, design, dimension, and materials. The only difference to the currently marketed devices is the change in surface treatment. There are additional processing steps for the new surface treatment when compared to the previous surface treatment.

Performance Testing:

Mechanical testing was performed to establish mechanical strength of the devices (ASTM F2077). Surface specific characterization and integrity testing were completed to support biocompatibility through ISO 10993-1. Pre-clinical testing performed included axial fatigue testing per ASTM F2077. Additionally, wear testing was done using a modified protocol of ASTM F1160 with particulate characterization. Biocompatibility per ISO 10993 was established through ISO 10993-1 assessment and an implantation animal model. The testing indicated that the Endoskeleton® devices are adequate for the intended use and substantially equivalent to the predicate systems.